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BRAND-NAME PRESCRIPTION DRUG PRICING

Lack of Therapeutically Equivalent Drugs and Limited Competition May Contribute to Extraordinary Price Increases

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Highlights

Highlights of GAO-10-201, a report to congressional requesters

Why GAO Did This Study

The growing cost of brand-name prescription drugs—FDA-approved drug products that typically have patent protection—is a concern for patients, payers, and providers of health care—particularly when price increases are large and occur suddenly. A 2008 congressional hearing by the Joint Economic Committee drew attention to some small market prescription drugs that had an extraordinary price increase—a price increase of 100 percent or more at a single point in time.

GAO was asked to examine extraordinary price increases for brand-name prescription drugs. Specifically, GAO examined the: (1) frequency of extraordinary price increases for brand-name prescription drugs from 2000 to 2008, (2) characteristics of the brand-name prescription drugs that had extraordinary price increases, and (3) factors that contributed to the extraordinary price increases experienced by these brand-name prescription drugs. To determine the frequency and characteristics of the brand-name prescription drugs that experienced an extraordinary price increase, GAO reviewed drug pricing and other data from a pharmaceutical industry compendium. To illustrate the factors that may contribute to extraordinary price increases, GAO developed case studies of six brand-name prescription drugs identified from the analysis of drug pricing data. These brand-name prescription drugs were selected based on factors including price, and the percentage and number of price increases.

View GAO-10-201 or key components.
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What GAO Found

From 2000 to 2008, 416 brand-name drug products—different drug strengths and dosage forms of the same drug brands—had extraordinary price increases. These 416 brand-name drug products represented 321 different drug brands. The number of brand-name drug products that had these extraordinary price increases represents half of 1 percent of all brand-name drug products. The number of extraordinary price increases each year more than doubled from 2000 to 2008 and most of the extraordinary price increases ranged between 100 percent and 499 percent. Almost 90 percent of all brand-name drug products that had an extraordinary price increase sustained the new higher price—by either having another increase in price or remaining at the increased price.

More than half of the brand-name drug products that had extraordinary price increases were in just three therapeutic classes—central nervous system, anti-infective, and cardiovascular. These therapeutic classes include drugs used to treat conditions such as fungal or viral infections, and heart disease. About half of the extraordinary price increases were for brand-name drug products that were purchased from drug manufacturers or wholesalers, repackaged, and resold in smaller packages to health care providers such as hospitals or physicians. However, some drug repackagers serve a niche in the drug market, and therefore may have a small share of the market in a therapeutic class. The majority of all extraordinary price increases were for drugs priced less than $25 per unit; however, a full course of treatment for some of these drugs could total several thousand dollars.

Based on interviews with experts and industry representatives, a lack of therapeutically equivalent drugs—both generics and other brand-name drugs used to treat the same condition—and limited competition may contribute to extraordinary price increases. The limited availability of therapeutically equivalent drugs may result from patent protection and market exclusivity, and the size of the market for a given drug. Patent protection and market exclusivity temporarily limit competition and thereby allow a drug company to recoup research and development costs and earn a return on its financial investment. Two of six case study drugs that had extraordinary price increases were patented at the time of the extraordinary price increase. The transfer of the rights to a drug and corporate consolidations among drug companies may result in fewer drug options and contribute to extraordinary price increases, according to experts. For example, the rights to four of the case-study drugs were obtained by a new drug company, and two of these drugs had an extraordinary price increase shortly after the rights to the drugs were purchased. Finally, experts and industry representatives noted that unusual events—such as disruptions in production due to shortages of raw materials—and other factors, including manufacturing issues, may also contribute to some extraordinary price increases.